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## U.S. House of Representatives Committee on Energy and Commerce Washington, DC 20515-6115

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May 14, 2008

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The Honorable Andrew von Eschenbach, M.D. Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Dear Dr. von Eschenbach:

The Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations have had a longstanding interest in the management and operations of the FDA Office of Criminal Investigations (OCI).

When it was administratively created in 1991, OCI started with about 130 criminal investigators. OCI now has about 190 criminal investigators, which is almost a 50% increase. The OCI budget has grown substantially as well: it was \$21.2 million in Fiscal Year 2000 (FY2000) and \$36.3 million for FY2006—a 71% increase in spending in only six years. However, the number of arrests and convictions has been just the opposite: 421 arrests and 353 convictions in FY2000; only 341 arrests and 279 convictions for FY2006. Doing the math, this means that the cost per conviction has more than doubled from \$51,000 in FY2000 to \$130,000 in FY2006.

At a time when we are contemplating how to ensure that FDA has sufficient resources to carry out its core missions of ensuring food, drug and device safety, we question whether continued funding and staffing of OCI at current and projected levels is the best use of scarce federal dollars. Further, as a policy matter, we question whether keeping investigations as a separate entity may have a detrimental impact on FDA's ability to effectively carry out its inspection activities.

In order to assist us in examining whether these resource trends and priorities make sense in light of the 21<sup>st</sup> century challenges facing FDA, we are seeking further information about OCI:

1. The budget request and the budget justification for OCI covering FY 2009.

- 2. Detailed expenses and accounting for FY2007, including the following breakdown with associated source of funding:
  - a. Salary, overtime, bonuses, awards, and pay grade (e.g., GS-10) for each individual in OCI. Please identify the number of OCI agents working with law enforcement task forces, the names of these task forces, and the salary/overtime/bonus/award expenses for these agents.
  - b. Number of hours OCI agents logged against each particular case, and number of hours and/or cost amounts for categories (e.g., counterfeit drugs, tampering) of cases worked.
  - c. Amounts paid from Central Funds for OCI leased office space.
  - d. An accounting of all other administrative expenses, sufficiently detailed to identify the particular activity for which disbursement was made. At a minimum, this should include expenditures related to field office inspections, training, firearms, non-salary personnel costs, and seizure and storage costs.
- 3. For FY2007, if OCI's claimed forfeitures include disgorgements, the amount generated from disgorgements. In addition, the amount of money OCI has recovered for OCI's budget from sharing in fines or forfeitures in cases, the amounts from each case and the name of the case, and where the asset forfeitures went.

Please provide responses to the following by June 6, 2008. If you have any questions, please contact Mr. Alan Slobodin of the Minority Committee staff at (202) 225-3641.

Sincerely,

John Shimkus

Ranking Membe

Subcommittee on Oversight and Investigations

cc: The Honorable John D. Dingell, Chairman The Honorable Bart Stupak, Chairman Subcommittee on Oversight and Investigations